REMARKS

Status of Claims

Claims 38-61 are currently pending. Claims 1-37 and 62-67 are cancelled without prejudice or disclaimer as to the claimed subject matter. Applicants reserve the right to pursue canceled subject matter in one or more continuation or divisional applications, as appropriate.

Claim 38 has been amended. No new matter is added.

Reply to Enablement Rejections Under 35 U.S.C. § 112, 1st Paragraph

Claims 38-44 are rejected for lack of enablement. The rejection is traversed to the extent it is applied to the claims as amended.

Claim 38, from which depend the remaining claims subject to the rejection, has been amended so that it is drawn to a method for treating a Chlamydia infection in a subject by administering to a subject in need thereof an effective amount of a therapeutic agent that disrupts the binding between cyclophilin and a cyclophilin binding partner.

To satisfy the enablement requirement, the specification need only teach one skilled in the art how to make and use the invention as claimed (without undue experimentation). It is the examiner's position that the specification does not provide sufficient disclosure so as to enable a method for treating or preventing a Chlamydia infection in a subject. The examiner supports the rejection of lack of enablement with argument, but not with specific evidence, that 1) "it is hard for one skilled in the art to

determine if all antibodies specific for cyclophilin A can be used to treat or prevent a Chlamydia infection in a subject"[1], 2) "fails to describe any antibodies that specifically bind cyclophlin A in the treatment or prevention of a Chlamydia infection"[2], 3) vaccination approaches have proved unsuccessful in combating Chlamydial infection, and 4) that there is no predictable way for the skilled artisan to determine what therapeutic agents would be effective without undue experimentation. No specific evidence is presented, however, that would doubt the objective truth of the current teaching that blocking the interaction between cyclophilin an its binding partners would effectively treat Chlamydia infection.

In order to establish a *prima facie* case of non-enablement, the examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. See In re Wright, 999 F.2d 1557, 1561-562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). A disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, *unless* there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. See In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). As stated by the court, it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up

[1] See Office Action at page 4.
[2] Id. at page 8.

assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

The threshold step in resolving this issue is to determine whether the examiner has met his burden of proof by advancing acceptable reasoning inconsistent with enablement. In re Morehouse, 545 F.2d 162, 165, 192 USPQ 29, 32 (CCPA 1976). Further, even a broad allegation that the disclosure is speculative, coupled with a recitation of various difficulties which might be encountered in practice, is not sufficient basis for requiring proof of operability. In re Chilowsky, 229 F.2d 457, 462, 108 USPQ 321, 325 (CCPA 1956). In the present case, Applicants respectfully submit that the examiner has not provided acceptable evidence that the claimed invention is inconsistent with enablement. At best, the examiner has made broad allegations that the disclosure is speculative and recited various difficulties which might be encountered in practice of the invention. This is not a sufficient evidentiary basis for requiring proof of enablement and a shifting of the burden of proof to appellant.

In addition, contrary to the examiner's contention, the specification provides guidance to one of ordinary skill in the art as to how to determine what therapeutic agents would be useful in the recited method without undue experimentation. The present inventors have discovered that the mechanism for Chalmydia infection may be mediated through a cyclophilin pathway. Indeed, Example 5 of the specification shows that antibodies to cyclophilin blocks Chlamydia infection of human cells thereby demonstrating that disruption of cyclophilin mediated pathways is important to inhibiting Chlamydia infection. Thus, it would reasonably appear that one of skill in the art could reasonably expected inhibitors of cyclophilin binding to be useful in the treatment of

Chlamydia infection. In this regard, the following passage from PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996) is instructive here.

> In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." Atlas Powder Co., v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:
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> > The test is not merely quantitative, since a *considerable amount of experimentation is permissible*, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. Ex parte Jackson, 217 USPQ 804, 807 (1982).

In the present case, even if a considerable amount of experimentation is required to determine which cyclophilin inhibitors are effective in blocking Chlamydia infection, such experimentation is routine to those of ordinary skill in the relevant art. Indeed, the specification discloses assays that may be performed to determine if the inhibitor is capable of blocking the interaction between cylcophilin and a cyclophylin binding

partner. This includes the assay disclosed in Example 5 that may be used to directly screen agents that block the Chlamydia infection in human cells.

Further, the possibility for inoperable embodiments within the scope of the claims is not a sufficient factor for nonenablement, as it is not a function of the claims to specifically exclude possible inoperative embodiments. Atlas Powder Co. v. E.I. DuPont de Nemours & Co., 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984); In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974). The Federal Circuit has cautioned against limiting a claimed invention to preferred embodiments or specific examples set forth in the specification. Texas Instruments v. U.S. Int'l Trade Comm., 805 F.2d 1558, 1562, 231 USPQ 833, 835 (Fed. Cir 1986). Accordingly, Applicants respectfully submit that the examiner has not met the burden of proof by advancing acceptable reasoning inconsistent with enablement.

For the foregoing reasons, Applicants request reconsideration and withdrawal of the rejection .

Reply To Rejections Under 35 U.S.C. 112, Second Paragraph

Claim 38 is rejected as indefinite for reciting the term "interaction." Applicants have amended the claim to delete this term. Applicants respectfully request withdrawal of these rejection.

Applicants submit that the application is in condition for allowance. Please charge any fees due or credit any overpayment due to the undersigned's Deposit Account No. 50-0311, Reference No. 22058-536.

Respectfully submitted,

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